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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,546	01/17/2001	Lynn E. Spitler	204372000901	8827

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

98/764,546

Applicant(s)

Spitler et al

Examiner

Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 15, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1642

1. The After Final Response filed September 15, 2003 (Paper No. 15) in response to the Office Action of June 12, 2003 (Paper No. 14) is acknowledged and has been entered. The Finality of the previous Action has been withdrawn Claims 61 and 56 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3 Applicant's argument drawn to the restriction of claim 56 from claim 61 has been found persuasive. Claim 56 is hereby rejoined with claim 61 and will be examined.
4. The following rejections are being maintained:

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. Claim 61 remains rejected under 35 USC 102(b) and claim 56 is rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 14, Section 5, pages 2-3.

The claims are drawn to a method to ameliorate a side effect, mucositis, myelosuppression or peripheral neuropathy of antineoplasia treatment in a subject, which subject has been treated with an anti-neoplasia agent which comprises administering to said subject a pharmaceutical composition comprising MTP-PE encapsulated in multilamellar liposomes.

Kleinerman et al, 1989 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in

Art Unit: 1642

multilamellar liposomes (abstract and p. 4665, col 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (p. 4665, col 2).

Kleinerman et al, 1992 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes (abstract and p. 212, paragraph bridging cols 1 and 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (abstract).

The method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes to the same population, that is subjects that had been treated with an anti-neoplasia agent thus the claimed method is anticipated because the method will inherently lead to the amelioration of mucositis, myelosuppression, peripheral neuropathy in the subset of these patients that present with mucositis, myelosuppression or peripheral neuropathy. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Applicant's arguments drawn to the rejection of claim 61 are relevant to the instant rejection.

Applicant argues that (a) the wording of claim 61 assumes that the subject is exhibiting mucositis at the time of treatment, otherwise the mucositis could not be ameliorated and a different patient population is targeted from the patient population set forth in the two cited documents since the population of the claims is the population that exhibits mucositis and not that which exhibits malignancies (b) the fact pattern here is in contrast to *Ex parte Novitski*, where the claims were directed

Art Unit: 1642

to a method of inoculating a plant against nematode infection where there was no requirement in these claims that the plant actually be infected by nematodes while there is a requirement here that the subject have mucositis and therefore the rejection applied by the Board in *Novitski* is inapposite in the present case.

The arguments have been considered but have not been found persuasive because (a') although the claim 61 infers that the patient has mucositis and claim 56 infers that the patient has the additional claimed side effects, it is expected that a subset of the subjects that have been treated with an anti-neoplasia agent would present with mucositis, myelosuppression or peripheral neuropathy thus the claimed population and a subset of the prior art population is the same, (b') although the fact pattern is slightly different, the issue raised and decided in *Novitski* is the same as the issue here, that is the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering an identical pharmaceutical composition to the same population, that is subjects that had been treated with an anti-neoplasia agent, thus the claimed method is anticipated because the method will inherently lead to the amelioration of all of the claimed side-effects of that neoplastic treatment.

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

Serial No: 09/764,546

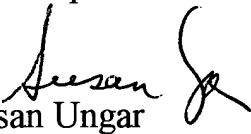
Page 5

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar

Primary Patent Examiner

November 26, 2003